

REMARKS

In the Office Action dated January 22, 2007, it was stated that claims 28-31 are withdrawn from further consideration as being drawn to a non-elected invention or species. Claims 44, 47 and 49 were objected to for certain language informalities. Claims 3, 5, 6, 24, 25, 27, 44 and 47-49 were rejected under 35 U.S.C. § 103 as being unpatentable over Caro (WO 95/09585) in view of Simon et al. (US 5,354,308, Simon) or Fontaine (US 5,443,498). Claims 3, 5, 6, 24-27, 44 and 47-49 were rejected under 35 U.S.C. § 103 as being unpatentable over Caro in view of Simon. Claims 12-16 and 45 were rejected under 35 U.S.C. § 103 as being unpatentable over Caro, Simon and Fontaine in further view of Schwartz et al. (US 6,015,387, Schwartz). For the reasons outlined in detail below, it is respectfully submitted that the pending claims are in condition for allowance over the applied references, as well as the remainder of the art of record.

Interview

The Examiner is thanked for the courtesy of providing an interview to applicants' representatives and attorneys on June 5, 2007. At the interview, one sample each of a helical stent and a straight stent or control were provided as evidence. All of the claims were discussed. Also discussed were the Caro and Simon references, as they were applied in the most recent Office Action. During the interview, Mr. Gilson explained how the claimed invention imposes a shape on the natural blood vessel, or other vessel in the body, in order to provide a swirl flow. Slides of photographs and test data were shown, which indicated that the restenosis area with a straight tubular stent was, in one

study, about twice that obtained by the use of a helical tubular stent. Also explained during the interview was that the Caro prior art reference WO 95/09585, the PCT reference, pertained to a helical tubular graft with closed walls that was designed to be placed mostly outside a vessel in the body, such as a blood vessel, and where the side wall thereof has no openings. It was also asserted during the interview that the stent, if any, placed in the Caro vascular prosthesis would conform to the helical tubular shape of the prosthesis, yet prevent kinking.

Independent Claim 24 and Dependent Claims 3, 5, 6, 12-16 and 25-27

Independent claim 24 and dependent claims 3, 5, 6, 25 and 27 were rejected as being unpatentable over Caro in view of Simon or Fontaine. It was stated that Caro discloses a vascular prosthesis that includes tubing which can include an internally inserted stent to give it a non-planar curvature that induces swirl flow. It was also stated that a stent could be inserted therein in order to keep the tubing open and to prevent it from collapsing or kinking.

Applicants submit herewith a declaration by Professor Caro, one of the applicants in the instant case and also the applicant in the Caro reference applied against the instant claims. Professor Caro notes in paragraph 8 of his declaration that in order to maintain the tubing 1 in the Caro reference, the PCT application, open and prevent collapse or kinking, it is possible to use a stent or other structural support internally to the wall of the tubing. As he notes in paragraph 9, any stent that he was aware of at the time of the filing of the PCT application was a cylindrical stent. To the extent that such stent was rigid, the stent would impose its own shape on the non-

planar curved shape of the tube 1 in the vascular prosthesis disclosed by Caro. This would be disadvantageous, since it would harm circulation by lessening the swirling flow of the fluid passing through the prosthesis.

On the other hand, if the stent was flexible, it would simply adopt the non-planar curvature of the tubing. Professor Caro doubts that a stent once installed in the tubing 1 of the prosthesis illustrated in Caro could be removed. But, if such stent could be removed, it would assume its normal cylindrical shape, whether the stent was rigid or flexible. In other words, the stent would not maintain any change imposed on the stent's normal cylindrical shape by the tubing, once the stent was removed from the tubing (see paragraph 10 of the declaration). In view of Professor Caro's declaration, applicants disagree with the assertion on page 4 of the Office Action that the internally inserted stent of Caro is, or could be capable of imposing a non-planar shape on the tubing. Instead, the tubing would impose its shape on any stent inserted therein, as Professor Caro notes in his declaration.

It was stated in the Office Action that member 8 (in Figs. 7 and 8 of Caro) can even be inserted into a blood vessel in order to receive flow therefrom. Reference was made to page 6, lines 24-30 of Caro. However, as Professor Caro further notes in his declaration, it is the hollow body portion 9 which is inserted within a vein or artery, either for receiving flow of blood from the branch member 8 or for delivering a flow of blood to the branch member. While the hollow body portion 9 may be inserted into a vein or artery, the curved branch member 8 is not. Rather, the free end of it is sutured to an adjacent blood flow conduit. As Professor Caro further notes, any stent would be located in the curved branch member which substitutes as a blood flow conduit for the

patient. Again, the stent does not impose its shape on the branch member 8. Rather, the branch member 8 imposes its shape on the stent member. As previously noted, only cylindrical stents were known to Professor Caro at the time of the filing of the Caro reference.

The secondary references to Simon and Fontaine do not supply those teachings which are absent from Caro. Simon shows a conventional cylindrical stent. As Professor Caro notes in his declaration, whether one looks at the sleeved stent in Figure 6 of Simon or at any of the other drawings in Simon, only a cylindrical or tubular stent is shown, wherein the entire structure is cylindrical in shape. See paragraph 11 of Professor Caro's declaration.

As to Fontaine, this reference similarly discloses a cylindrical stent. However, Fontaine also mentions a curved stent (col. 6, lines 14-19). As Professor Caro states in paragraph 12 of his declaration, the Fontaine curved stent would have a central axis which possesses a two dimensional or planar curvature. Such a planar curvature would not induce a swirling flow, as a three dimensional curvature is required to do so.

In contrast to the invention recited in claim 24, the Caro reference pertains to a prosthesis including a tube 1 having a solid outer wall. Thus, even a stent, of whatever shape, placed within the tubing 1 in the Caro prosthesis would not meet the limitations of claim 24. More particularly, even if such prosthesis were inserted into a vessel and the stent within the prosthesis would form a non-planar three dimensional at least partially helical shape, the tubing 1 would not have walls with openings therein so that when the stent is inserted into a vessel, the interior wall of the vessel is exposed via the openings to fluid flow along the vessel. Even in the instance where the tubing shown in

Caro is inserted into a vessel, it is only the tubing 9 which is inserted, not the non-planar curved branch member 8. However, even if the non-planar curved branch member 8 were inserted into a vessel, the interior wall of the vessel would not be exposed to fluid flow along the vessel since there are no openings in the non-planar curved branch member 8 shown in Figs. 7 and 8 in Caro. Also, as mentioned, the non-planar curved branch member 8 is not meant to be inserted within the walls of an intact vessel in the body of a patient. Rather, as Professor Caro notes in paragraph 14 of his declaration, the free end of the curved branch member is meant to be sutured to an adjacent blood flow conduit.

Moreover, any stent added to the tubing 1 of the Caro reference would not be capable of imposing a three dimensional at least partially helical shape on the central axis of an intact vessel in which the stent is inserted. First, in Caro, the stent would only be inserted into the prosthesis, whether that be the tubing 1 shown, for example, in Figs. 5 and 6 of the Caro reference or the non-planar curved branch member illustrated in Figs. 7 and 8. Neither is meant to be inserted into an intact vessel. Second, as noted by Professor Caro in paragraphs 9 and 10 of his declaration, the stent, if it imposed any shape at all on the prosthesis, would impose a cylindrical shape thereon. Instead, it is the prosthesis which would impose its non-planar three dimensional at least partially helical shape on the stent. However, this would occur only while the stent was located within the prosthesis. If the stent were to be removed, and Professor Caro rather doubts that this could occur, the stent would resume its normal cylindrical shape. Therefore, any such stent would not meet the limitations of independent claim 24.

Even the combination of Fontaine and Caro would not meet the limitations of

independent claim 24. More particularly, even if the curved stent of Fontaine were placed in the tubing 1 of the vascular prosthesis in Caro, the end result would not be the claimed invention. The so modified Caro tubing would not result in a stent of a non-planar at least partially helical shape which would be capable of imposing the three-dimensional at least partially helical shape on the central axis of an intact vessel, other than a graft, which internally supports an interior wall of that vessel part, with the walls of the tubing having openings therein so that the stent when inserted into the vessel the interior wall of the vessel is exposed via the openings to fluid flow along the vessel. As a result, independent claim 24 patentably defines over Caro alone or Caro in view of either Simon or Fontaine. Moreover, claim 24 patentably defines over the remainder of the cited references as well.

Another rejection propounded on page 4 of the Office Action was Caro in view of Simon. In this regard, it was stated that Simon teaches that it was known in the art to make a stent with openings in the walls thereof. Therefore, the Examiner's position is that it would have been obvious to utilize the stents of Simon as the stent of Caro for the same reason that Simon utilizes the same within vessels or grafts.

However, as noted in paragraph 11 of Professor Caro's declaration, the Simon stent is cylindrical or tubular in configuration as shown in the several drawings of Simon. Therefore, if the Simon stent were inserted into the tubing 1 of the Caro prosthesis, at best, it would conform to the shape of the Caro tubing. To the extent that the Simon stent would not conform to the shape of the Caro tubing, then it would impose its shape on the non-planar curved shape of the Caro tubing 1, reducing the curvature of the tubing. As noted in Professor Caro's declaration, this would be disadvantageous. See

paragraph 9 of the Caro declaration.

Even if the stent of Simon is inserted into the tubing 1 of the Caro vascular prosthesis, it is the tubing 1 which imposes its shape on the stent, rather than the stent imposing its shape on the tubing. In any case, such a combination would not meet the limitations of claim 24, since the Caro tubing with the stent inside would not have the necessary openings to allow the interior wall of the vessel to be exposed via the openings to fluid flow along the vessel. Therefore, it is respectfully submitted that claim 24 also patentably defines over the asserted combination of Caro and Simon.

Dependent claims 3, 5, 6 and 25-27 further patentably define the detailed subject matter of their parent claim or each other. As such, these claims are also believed to be in condition for allowance over the applied combination of references, as well as the remainder of the art of record.

Dependent claims 12-16 were rejected under 35 U.S.C. § 103 as being unpatentable over Caro, Simon and Fontaine in further view of Schwartz. Schwartz was said to teach monitoring devices. It was asserted that it would have been obvious to include a monitoring device in the Caro device for the same reasons that Schwartz uses the same in order to monitor the blood to see if the desired swirl flow is occurring. However, Schwartz fails to teach those elements which are clearly missing from the applied combination of references. Therefore, dependent claims 12-16 also patentably define over the asserted four way combination.

Independent Claim 44 and its Dependent Claim 45

Independent claim 44 was similarly rejected over Caro in view of Simon or

Fontaine. Moreover, claim 44 was rejected over Caro in view of Simon alone.

For the reasons outlined in detail above in connection with claim 24, it is respectfully submitted that even the combination of a) Caro and Simon or Fontaine or b) Caro and Simon does not render unpatentable the stent recited in claim 44.

Dependent claim 45 was rejected as being unpatentable over Caro, Simon and Fontaine in further view of Schwartz. Caro was said to fail to disclose the monitoring device as claimed. Schwartz was said to teach that such devices were known in the art at the time of the invention. It was asserted that it would have been obvious to include a monitoring device in the Caro device for the same reasons that Schwartz uses the same in order to monitor the blood to see if the swirl flow desired is occurring. However, Schwartz does not provide those teachings which are so clearly absent from Caro, Simon and Fontaine, even in combination. Therefore, claim 45 is also believed to be in condition for allowance over the applied combination of references.

Independent Claim 47 and Dependent Claim 48

Claims 47 and 48 were similarly rejected over the combination of Caro, in view of Simon or Fontaine or Caro in view of Simon. For the reasons outlined in detail above, it is respectfully submitted that these claims are also patentable over the applied combination of references, as well as the remainder of the cited art.

Independent Claim 49 and Dependent Claim 50

Claim 49 was similarly rejected as being unpatentable over Caro in view of Simon or Fontaine or Caro in view of Simon. For the reasons outlined in detail above, it

is respectfully submitted that claim 49 patentably defines over the applied combination of references, as well as the remainder of the cited art.

Dependent claim 50 is added herein. This claim depends from claim 49 and recites that the hollow tube comprises a shape memory alloy. The teaching of such a shape memory alloy is clearly present in the instant application as filed. More particularly, it is stated in the instant specification as regards to Figures 6A and 6B that the material used is preferably a shape memory alloy to facilitate insertion of the stent (see lines 19-21 on page 7). Therefore, no new subject matter is being added thereby. Since claim 50 merely further patentably defines the detailed subject matter of its parent claim, claim 49, it is respectfully submitted that claim 50 is also in condition for allowance over the art of record.

In view of the foregoing, it is respectfully submitted that all of the pending claims are in condition for allowance over the applied combination of references, as well as the remainder of the cited art. Allowance of the instant case is therefore respectfully requested.

Respectfully submitted,

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Date



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